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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/609,132   | 06/26/2003  | Andrew J. Boeckle    | 0133.00             | 6677             |
| 21968  | 7590        | 11/17/2004           | EXAMINER            |                  |
| NEKTAR THERAPEUTICS<br>150 INDUSTRIAL ROAD<br>SAN CARLOS, CA 94070 |             |                      | HUYNH, LOUIS K      |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3721                |                  |

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/609,132 | <b>Applicant(s)</b><br>BOECKLE ET AL. |  |
|                              | <b>Examiner</b><br>Louis K. Huynh    | <b>Art Unit</b><br>3721               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.  
     4a) Of the above claim(s) 47-58 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-46 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/5/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-46 in the reply filed on July 23, 2004 is acknowledged. The traversal is on the ground(s) that the examination of both groups would not pose an undue burden on the Office. This is not found persuasive because Groups I and II are related as process of making and product made and the product itself does not depend on the process for making it. Therefore, the search for a pharmaceutical package is not expressly included in searching for the method and the apparatus for filling a chamber with a powder.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 47-58 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 23, 2004.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8, lines 1-2: "the vibratable member" lacks proper antecedent basis.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al. (US 5,753,302).

With respect to Claims 1-7, 22 and 23, Sun discloses an acoustic dispenser (1710) including a hopper (1780) adapted to contain pharmaceutical powder, and a vibrating membrane (1760) that vibrates at a selected frequency, preferably at resonant frequency (col. 8, lines 41-54) and disturbs the air within the hopper (1780) to dispense the powder through the outlet.

With respect to Claims 8 and 24, the membrane (1760) of the acoustic dispenser (1710) of Sun is operated at audible range having known frequency of about 20Hz to about 200kHz, which includes the range of about 10Hz to about 1kHz as claimed.

With respect to Claims 19-21, the hopper (1780) is an enclosure having side wall and a cover, wherein the cover comprises the membrane (1760).

7. Claims 1, 9-13, 15-18, 22, 25-34, 38-42 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Parks et al. (US 5,826,633).

With respect to Claims 1, 9-13, 15-18, 22 and 25-30, Parks discloses an apparatus for filling a receptacle (12) including a hopper (18) adapted to contain pharmaceutical powder (28) and having an outlet (46), a vibratable member (34) capable of disturbing air within the hopper

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(18) by vibrating a member (22) in a longitudinal direction of the member (22) (col. 4, lines 34-36) that contact the powder (28), a metering chamber (56) disposed on a transfer wheel (16) that rotates between a receiving position and an ejecting position (FIGS 5-8), and a blister receptacle (12) for receiving the metered powder.

With respect to Claim 31-34 and 38, Parks discloses a method of filling a chamber including the steps of: provide a pharmaceutical powder (28) in a hopper (18), disturbing a medium (22) in the hopper (18) to fluidize the powder, passing the fluidized powder through an outlet of the hopper (18) into a metering chamber (56), rotating a transfer wheel (16) from a receiving position to a transfer position, and transferring the powder in the chamber (56) to a receptacle (12). Note that as the medium (22) is disturbed, the air which is a form of gas within the hopper is also disturbed.

With respect to Claim 39, the receptacle (12) with the filled powder is sealed (col. 17, lines 27-28).

With respect to Claim 42, Parks discloses a method of filling a chamber including the steps of: provide a pharmaceutical powder (28) in a hopper (18), vibrating a member (34) spaced from the powder (18) to fluidize the powder, and passing the fluidized powder through an outlet of the hopper (18) into a metering chamber (56).

With respect to Claim 46, the method of Parks further including the step of vibrating a second member (22) that is in contact with the powder to fluidize the powder.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parks et al. (US 5,826,633).

The apparatus of Parks meets all of applicant's claimed subject matter but lacks the specific teaching of the receptacle being a capsule. However, the receptacle is a work piece that does not form a part of the claimed apparatus; thus does not patentably distinguish the claimed apparatus from the applied prior art. Furthermore, capsule is a well known form of containing pharmaceutical powder; therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have modified the apparatus of Parks by having provided the receptacle in the form of capsule since modifying the existing apparatus to accept one form of receptacle such as capsule over other form of receptacle such as blister package is within the knowledge of the skilled person in the art.

10. Claims 35-37 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parks et al. (US 5,826,633) in view of Sun et al. (US 5,753,302).

With respect to Claims 35 and 43, the method of Parks meets all of applicant's claimed subject matter but lacks the specific teaching of the vibration is generated by vibrating a membrane.

However, Sun discloses a method for dispensing pharmaceutical powder that includes a step of vibrating a membrane (1760) to fluidize the powder and to force the fluidized powder out of the hopper (1780).

Therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have modified the method of Parks by having provided a membrane and having vibrated the membrane to fluidize the powder in the hopper, as taught by Sun, so that the vibration of the membrane forces the fluidized powder in the hopper through outlet much faster.

With respect to Claims 36 and 44, Sun teaches that the vibrating membrane (1760) vibrates at a selected frequency, preferably at resonant frequency (col. 8, lines 41-54) and disturbs the air within the hopper (1780) to dispense the powder through the outlet.

With respect to Claims 37 and 45, Sun further teaches that the membrane (1760) is operated at audible range having known frequency of about 20Hz to about 200kHz, which is includes the range of about 10Hz to about 1kHz as claimed.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure has been cited on form PTO-892 along with the applied prior art.

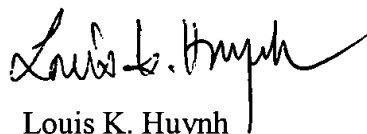
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (571) 272-4462.

The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

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13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (571) 272-4467. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louis K. Huynh  
Patent Examiner  
Art Unit 3721

November 15, 2004